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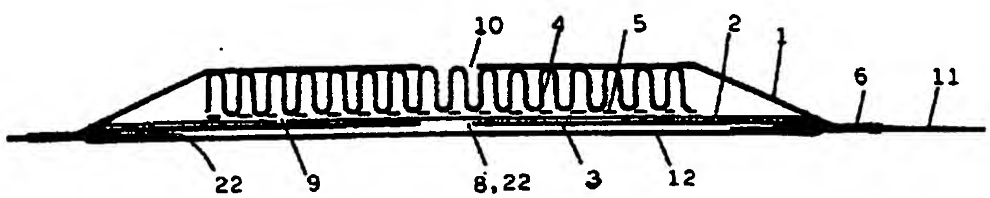
(54) Title: AUTOMATIC VALVE FOR VENTILATION OF STOMYBAGS



(57) Abstract: Valve for automatic ventilation of stomybags and for control of gasflow through a deodorizing filter. In the main figure, which is number 2, the pressure control valve is built in a flat capsule with a top (1), a bottom (3) and a tightening film (2). Between the tightening film and the top of the valve is an elastic pressure plate (4) with a pressure surface (5), which holds the tightening film against the bottom of the valve, when the valve is closed. The valve is mainly made of polymeric materials. The valve is flexible and flat and can be placed both on plane and curved surfaces of bags or containers. The valve opens and closes defined interval for the existing pressure in the stomybag (11). Flatus will passes through the opening (8) in the bottom and opening (10) in the top of the valve, as well as it passes the small opening (9) in the tightening film. If the pressure plate or any part of the valve is made of soft, viscous elastic material of porosity, then valve can be opened manually as well. The valve will in this case remain open for a short period of time and close continuously. For reasons of protection the valve has a membrane of porosity mainly produced of polytetrafluorethylen based on a material also of porosity and heatsealable. The pressure plate (4) can be impregnated with activated carbon. The valve can be coupled to gas filter of combined with a gas filter.

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Automatic valve for ventilation of stomybags.

and others in the same category and for control of gas flow through a filter of deodorizing.

The valve in accordance with the invention is a pressure control valve, which can be combined with a filter of deodorizing and it can attached to a stomybag.

The valve will open by itself as soon as there is a little over pressure in the bag and will close again, when the pressure decreases. Giving the special design of the valve, it can be opened manually and after a delay of time the valve closes again by itself.

Many patents concerning valves and methods of airing stomybandages and stomybags are known. A american patent US 5401264 describes an elastic, dome-shaped valve. In the top of the dome is a sharp cut. The valve is attached over a carbon filter to a stomybag. The opening of the valve, the mentioned sharp cut, is normally closed. It can be opened pushing two fingers against the dome holding the fingers at the endings of the cut. The valve can only be opened manually and it closes at once, when the push stops. If the flow through the valve is low due to the concern of the gas filter, one has to hold this valve open with the fingers for 15 – 30 seconds to empty the bag for air.

Other patents concerning valves been served manually are known, among these US 5372594, US 4232672, US 5622569, US 5693035 and EPO 868892. An international patent WO 83/ 04081 concerns a pressure control valve with a carbon filter and a valve-cone made of a firm material. The valve opens and closes, when the pressure increases and decreases in the bag. Without a controlled flow through the valve the period of function either remains too long or the flow is too high. A long function period is inappropriate and presupposes as well, that the valve is to be untouched by the user throughout this period. Otherwise the valve will open and close all the time, due to the mechanical influence from the outside. A high flow through the valve causes the carbon filter of the valve to malfunction.

A danish patent 158133B/1990 concerns a method to increase the fall of pressure over the carbon filter on a stomybag. It describes the known disadvantages of filter of deodorizing. The known carbon filters of stomybags have a flow through the

filter of around 30 ml/min up to over 600 ml/min at a pressure of 10 cm WC (Water Column). Pressure means here and in the following, that part of the pressure in the container or stomybag, which is above the pressure of the atmospheric.

A carbon filter on stomybags only functions suitable by a low flow. The fall of pressure over the filter is in that way aimed to become so big, that the flow for the function of deodorizing of the filter becomes optimum. On the other hand the decrease of pressure may not be to high, because it causes the bag to blow up as a balloon. This feared phenomenon is called ballooning.

Even a flow of 30 ml/min is all too high in practice, because the intestine through the stomy only yields an average 1 – 2 ml/min. The flow in this case is similar to flow passed through a very small hole made by a needle. As the filter unlike the valve can not limit the flow by low pressure, the unfortunately will happen, that a vacuum in the bag is build up. The bag will empty completely and the walls of the bag collapse around its contents and a so-called pancake is build.

The walls of the bag, which consist of smooth foil of plastic, are glued together in the bag and around the stomy by adhesive faeces. Now the bag is no longer soft and comfortable to wear. It is stiff as a plate or curled together in a hard lump. By the movements of the body the cloth pulls the plat or the lump form side to side and these movements spreads to the skin-plate and further on to the skin surrounding the stomy.

In the situation faeces has been pressed out through the stomy and forms a lump of 2 – 4 cm in front of the stomy. As the faeces can not move on the walls of the bag, there will be an increase in the risk of a blocking and clogging the filter. This will sooner or later cause the bag to blow up.

Faeces, which is sufficient liquid, will force its way out through the filter, if the opening of the filter in the wall of the bag is not protected by an effective membrane. By day faeces will be absorbed of the underwear and by night on the bedlinen given it a very smelly odour and the humidified filter will lose its ability to dedorize.

If the filter is clogged, the bag will be blown up in a few hours and be noticed by the carrier as lump outside the cloth. When the bag is blown up the increase in pressure in the bag will cause the skin plate to loosen itself from the skin especially below the stomy.

To avoid the mentioned inconveniences of the filter, a sheet of labels in an amount similar to the amount of bags is enclosed in the packing delivered. Users of bags, which has experienced pancaking and a loose plate of skin, are inclined to put a label over the opening of the filter before using. Now the bag is gas tight. In that way the bag during the day has to be emptied for intestine gas, which only can take place on a toilet, because normally the underwear covers the bag. If the stomybag for instance sits below the belt and on the left part of the stomach. it is difficult for the user to see the label and to lift it by use of nails. When the filter is open, the air is pressed out of the bag. By a high flow through the filter the outflow of gas smells badly.

One-part stomybag can only be aired as described, while a two-part stomybag with a separate skin-plate can be aired by loosening the coupling-rings. When the expensive deodorizing filter is blocked with a label, the filter is superfluous and could be replaced by a needle hole covered with a label. Almost all colo stomybags and a growing part of ileo stomybags are delivered with a deodorizing filter.

The intend of the invention is to provide an all-round control valve for stomybags and similar, which can assist in using stomybags without being emptied complete for air and automatic limiting the amount of gas in the bag upwards.

The valve can be design in such a way, that it opens at a definite pressure, the opening pressure of the valve, which is a little higher than the closing pressure of the valve. Is the pressure plate of the valve in two parts, the valve can necessarily be opened manually. After being opened manually, a two-part valve with a delay of time gradually closes by itself.

When a stomybag with filter is changed, the new empty bag will lies flat between the stomach and to the cloth. As the filter allows a flow out of the bag, which is larger than the amount of gas, that the stomy minute by minute produce, the bag easily is emptied for air assuming the opening of the filter is not blocked.

Faeces, which given off from the stomybag, may change consistency from firm to liquid. Such a change in consistency may happen from day to day or even during the same day. The firm and formed but not pasty faeces find its way down to the bottom of the bag, where it stretch the bag at the lower part. Often faeces having a formed but pasty and adhesive consistency moulding into a pancake.

The filters opening, which as mentioned is similar to a tiny needle-hole, has an area almost independently of the gas pressure. To avoid ballooning as mentioned neither may the flow through the filter be too high or too low.

Contrary to the filter, the area of opening is variable for the valve in accordance with the invention. The area grows exponential with the pressure and it is zero or almost zero below a defined pressure in the bag.

Deciding for the designing of the valve for a stomybag is knowing following facts: the amount of gas from the intestine delivered to the bag, the size of the stomybag and the pressure in the bag, which again depends on the outside pressure on the bag and the degree of filling.

In non-fiction literature the normal liberation of intestine gas from an adult is set to less than 100 ml pro hour or 1.7 ml/min. For a vegetarian, who covers half of his need for calories with beans, is measured 168 ml of gas in one hour or 2.8 ml/min.

For an adult was, more up to date, measured an average amount of liberation of gas to 1.4 ml/min in a period of a week. The liberation of gas from the intestine proved to be 22 % lower at night than by day.

As the following example show, stomybags during 24 hours period is exposed for a considerable variation of external pressure from cloth, breathing, cough, bending together in the hip etc.

An adult carries an 800 ml stomybag on his left part of the stomach just below the belt. The bag contains 250 – 300 ml of air. Gas tight an opening in the bag is connected to a water column meter.

When this adult sitting in a comfortable chair a pressure in the bag is measured to 12 – 20 cm WC. When yawing or leaning forward in the chair the pressure rises to 30 cm WC. When the left ankle being placed on the right knee the pressure is measured to 38 cm WC. When raising up and putting the left foot on the edge of a chair to tie his shoe the pressure rises to 55 cm WC. When further leaning forward towards the shoe the pressure rises to 70 - 90 cm WC.

When this adult stands upright and wears loose clothes or lies on his back covered with a blanket or a light duvet, the pressure in the bag is 0.5 – 2 cm WC. As already mentioned means by pressure, that part of the pressure in the container or bag, which is above atmospheric also called over-pressure.

If the total contents in the stomybag is below 100 ml as mentioned above the corresponding pressures are considerable lower. On the other hand the corresponding pressure is considerable higher, if the bag is half or more blown up. By lasting high pressures the skin-plate will loosen from the skin especially below the stomy. Afterwards the loosened area of formed slip easily spreads out to the edge of the skin-plate.

In figure 21 values belonging together for the internal pressure in the bag, measured in cm WC, and the total contents of faeces and gas, measured in ml, are plotted for discrete values of the external pressure on the bag, measured in N. The measurement is carried out for a stomybag, which is able to contain 800 ml water and to be blown up to a content of 850 ml air. It appears from the curves, that the internal pressure in the bag even at a relative low external pressure on the bag increase strongly as the degree of filling in the bag increases. Confirming the wellknown fear of ballooning is legitimate.

In a few of hours situations may occur for a person wearing a stomybag with a valve and carbon filter, where the bag is no longer exposed for external pressure to that degree of pressure, for which the pressure in the bag surpasses the opening-pressure of the valve. The bag is at that time blown up. This situation may occur, if the person wears very loose clothes and as mentioned is standing up and not moving for a period of time or if the person lies on his back with loose night clothes or is covered by a light duvet. However in practise underwear, other tight-fitting clothes and movements of the body usual causes, that there in a sufficient long period of time arises a sufficient high pressure in the bag, that the valve will be held open throughout this period. At night one has to wear night clothes, which gives a smaller weight pressure on the bag. However when sleeping movements may give an external push on the bag, which opens the valve and in this way keeps the amount of gas in the bag at an acceptable level.

To rectify this lack of ventilation of the bag for a longer period of time as mentioned above, the valve when closed can be manufactured to have a low controlled flow. Finally the pressure plate of the valve can be carried out in such a way, that it can be opened manually.

In accordance with the invention the construction to prefer is the pressure control valve with a divided pressure plate, where the one part is made of viscous elastic

material, which may be a viscous elastic polyurethan foam. Flatten the viscous elastic part of the pressure plate with a finger, which can be done from outside the cloth, the valve remains totally open for instance in a minute as shown in figure 20 and then gradually closes again by it self. The viscous elastic foam slowly expands to its originally shape and in that way the valve closes gradually in a few minutes. If the pressure control valve is constructed in this way, the valve has a controlled lake of tightness, when the valve is closed and a part of the intestine gas will lake out slowly through the valve and filter, no matter how low the pressure is, except zero. If this flow is at around 0.5 ml/min, than at around a third part of the intestine gas will passes through the filter by this ideal low flow. Only to a small degree will the pressure control valve have to open with a flow not higher than a few ml/min.

An 800 ml stomybag is only 1 cm thick, when the total flow of faeces and gas in the bag is 250 ml. The thickness of 1 cm is measured as the distance between two thin parallel plates, which is held together against each site of the bag with its contents.

Using a similar measuring arrangement. Fixing the one plate, exposing the other liberate plate for a pressure, allowing one to setup a table for values belonging together of the total amount of air in the bag, the pressure in the bag and the outside pressure on the liberate plate.

In figure 21 shows curves for discrete values of the outside pressure on the bag measured in N. The curves shows the following, that with a already blown up bag even a relatively low constant outside pressures will cause a strongly increase of pressure inside the bag.

Both a stomybag with a filter and a valve and a stomybag with a closed filter will be blown up. The first will be aired automatically wherever the person is, because a low flow will passes through the valve, without the user noticing anything. But the other will be blown up and be uncomfortable. It is to be aired on a toilet by taking off the label to open the filter, if the filter is not already clogged.

For special use a tight valve is to be prefered, the valve can be made tight by preparation of the tightening-surface of the tightening-film with a non volatile liquid as silicone oil.

A valve, mounted as an intermediate protection between the stomybag and the gas filter, can result in the filter more easily releases condensed water, which possible has been formed in the filter.

The valve should be a protection by a micro porous protection membrane, which mainly consist of a layer of non sintered polytetrafluorethylen on a supporting material made of porous, heat-sealable substance. The membrane must have a pinhole size around 1 – 3 μm. Perforated, porous or micro porous material or others can also be used.

The pressure control valve can be placed on the side of the carbon filter on the stomybag and connected to the filter with a gas tight canal. However the construction preferred is valve and filter forming a unit.

The valve in accordance with the invention is constructed as a pressure control valve. The valve may also be constructed in such a way, that it works as a self-closing valve with delay of closing. The valve may be combined with or built together with a deodorize filter. The valve can be mounted outside or inside of the wall of a gas tight stomybag and other bags where an unwanted over pressure may arise.

Mainly the valve is flat and flexible. It may be circular, rectangular or have other shapes. Figure 1 shows the main components. The top (1) and the bottom (3) of the valve moulds in a capsule. The tightening film (2) close the valve against the direction of the gas-pressure. It is attached against the valve-bottom of the pressure plate (4) with the pressure surface (5). The bottom of the valve, the tightening film and the top of the valve have respective the openings (8, 9 and 10). The gas flow through these openings, when the valve is open. At last the gas-permeable protection membrane (12) is a part of the construction. The protection membrane prevents consistent and liquid contents to force its way out through the valve.

In figure 2 the valve is shown jointed in the periphery (6) and attached on the edge of the opening (22) in the wall of the container (11) by heat-sealing, glued or attached in an other manner.

The tightening film (2) may be smaller than the capsule of the valve as shown in figure 3 or having great openings (9) as shown in figure 13. In the preferable design of the valve the tightening film is attached gas-tight to the top of the valve and provided with a little hole or a needle-cut-hole cut by a lancet-shaped needle.

The valve is not to be opened by an over pressure in the container, if the tightening film (2) closes tight against the top of the valve (1) in direction of the gas-pressure as shown in figure 3. This valve can be opened manually and automatically close with a delay of time, when some part or the whole pressure plate (7) is made of a viscous elastic material.

It is possible to use thin films of plastic for the top, bottom and tightening film of the valve, which shall function by a pressure normal not exceeding 20 cm WC. Exposed by the maximal pressure the components for the valve generally speaking must have the strength only deforming elastic and not plastic. Figure 4,5 and 6 are the tops for the valves (1) made of a relative stiff material shaped in the same shape as the pressure plate (4).

The pressure plate of the valve must be elastic and porous. The pressure plate or a part of the pressure plate must be made of a porous and viscous elastic material for a valve to be opened manually and closing by itself. Open celled polyurethan foam can be made in several degrees of viscous elasticity. Among others soft elastic and open-celled foam and elastic fibre material becomes viscous elastic by preparation with known pressure-sensitive adhesives.

The pressure plate or a part of the pressure plate can by preparated with activated carbon and a part of the surface of the pressure plate can by made gas-tight and the prepared part of the pressure plate can in that way deodorize the gas flow.

The pressure plate (5), which turns against the tightening film (2), can totally or partly consist of its own rough structure. It can consist of a grained coating or a depth-embossed film as shown in figure 14.

The rectangular shaped valve, as shown in figure 11 and 12, can be made in strips, where the separate valve is cut off and heat sealed afterwards.

A gas permeable protection membrane (12) manufactured of a perforated, porous or micro-porous material, is attached as shown in figure 4,5 and 6 on the bottom of the valve (3) or on the inside wall of the bag above the airing opening as shown in figure 2 and 10.

In figure 4 the membrane is heat sealed along the periphery (14) of a heatseable film (15), or attached to the film in another way.

The gas flow from a stomybag passes at first a valve and next a gas tight canal to the filter on the bag.

As shown in figure 5 and 6 the valve and filter can be manufactured as a unit, which can be placed outside or inside the stomybag.

The tightness of the valve can be improved by preparation of the underside of the tightening film with a non volatile liquid, as liquid silicone, paraffin, glycerine, sorbitol etc.

The tightness of the valve can be reduced by doing the opposite tightening surface for the tightening film and the bottom of the valve less smooth material for the film with more rough surface or with a slightly embossed surface.

The valve in accordance with the invention can be manufactured in such a way, that it closes in the direction of the pressure, as shown in figure 3. In this version an over pressure in the bag or container can not open the valve. If the pressure plate (7) is made of a viscous elastic porous material, the valve can be opened manually with a push of a finger. The valve will remain open for a minute or so and then again gradually closes in a few minutes.

In figure 8 is the one part of the pressure plate manufactured of a common soft foam (4), the other plate is manufactured of a viscous elastic open celled polyurethan foam (7), which clings easily to both the top film (1) and the tightening film (2). The pressure plat is pressured flat by a finger, while the thin tightening film (2) is lifted up over the wall of the bag (11), which forms the bottom of the valve. The valve is opened for a gas flow trough the openings (8, 9 and 10)

In figure 9 the viscous elastic pressure plate (7) is non adhesive on the surface to the tightening film (2), but it is glued to the top of the valve (1). The static pressure in the bag has lifted the thin tightening film up over the bottom of the valve and in this way the valve has been opened.

If the pressure plate is manufactured of a special soft, viscous elastic foam and the valve is exposed to a short-time powerful rising of pressure, the pressure plate can be pressured flat between the tightening film and the top of the valve (1) and the over pressure has opened the valve. The valve remains open for a short period of time and afterwards closing by itself.

Polyurethan foam with open cells is manufactured by many manufactures in viscous elastic qualities. Soft elastic and open celled foam, elastic fibres etc. can be given viscous elastic characteristic by preparation with known pressure-sensitive adhesive.

A soft polyuerethan foam based on polyether with open cells and a density of 18 kg/ m³ is preparated with a pressure sensetive adhesive called Vinnepas® EAF 60 from Wacker-Chemie polyether GmbH. This product is an aqueous dispersion of copolymer on basis of vinyl acetate and acrylic ester.

After being flattened by a finger a piece of foam with this preparation has a thickness of 0.5 mm, if the originally thickness was 4 mm. At the beginning a piece of foam expands slowly, if it has been pressed together, later it expands faster. After 5 minutes the thickness of the piece is around 4 mm again. Figure 20 shows the rate of flow versus the rate of time for a valve, when the viscous elastic pressure plate expands after it has been pressed together and afterwards it will slowly closing the valve.

Figure 10 shows the opened pressure control valve. The static pressure in the container holds the tightening film (2) and the pressure plate (4) against the bottom of the valve (11). In this case the bottom of the valve is the wall of the container or bag. The air from the container streams through the openings (8, 9 and 10). The pressure plate presses the tightening film tight against the openings (8 and 9), when the pressure has fallen to the closing pressure of the valve.

The closing pressure of the valve is defined as the pressure for a flow less than 0.03 ml/min. The opening pressure of the valve is defined as the pressure for a flow through the valve to be measured about 0.15 ml/min.

If the opening (9) in the tightening film (2) is great compared with the proportion of the opening (8) in the bottom of the valve (3), and the pressure plate (5) is relative smooth, the valve will first opens for a relative high pressure. Figure 13 is an example of that type, which also includes valves with a tightening film not heat sealed to the capsule of the valve.

The tightening film (2) is lifted up from the bottom of valve as shown in figure 10, if the opening (9) in the tightening film (2) is considerable smaller than the opening (8) in the bottom of the valve (11). The static pressure must only be a bit higher than the

closing pressure of the valve. This type of valve is characterized by that it can be manufactured to have a pressure of opening close to the pressure of closing.

Although it is possible to measure a small flow through the valve, lifting of the tightening film from the bottom of the valve will be invisible, if the pressure in the container is just able to open the valve. This is also the case, if the tightening film (2) and the bottom of the valve is smooth and if the pressure face (5) is smooth and with a fine texture.

The valve is opening relative easy and with a little flow, if the pressure plate (5) on the pressure plate (4) has a rough regular texture. In figure 14 is a valve shown with a pressure surface (5), which is made of an embossed polyethylen film. The embossment is 0.5 mm in depth and the distance between the tops of the embossments or press-points (25) is 1.5 mm. The tightening film has a thickness of 0.03 mm.

If the static pressure in the container is just able to open this valve, the flow of gas passes through some small canals (26), which are conneced to the opening (8) with the area outside the periphery of the pressure plate. Later on the flow passes through the openings (9 and 10). The canals are inversible or hardly visible when they are created, but grows by raising pressure.

The canals (26) in figure 14 are built in the thin tightening film, which is pressed upwards by the pressure of the gas between the pressure points (25) in the pressure surface (5). The flow through the valve raises relative slowly by increasing pressure. Even through the total area of the canals grows visible, but the pressure fall is great through the thin canals in that interval of the pressure. In the interval of pressure where the canals exist, the flow through the valve and the filter is small. The tightening film is lifted up from the bottom of the valve by a still raising pressure and the valve is opened totality, which courses a sudden raising of flow. If the pressure surface (5) has a regular texture or embossing, it is possible to recognize the pattern of the pressure surface in the system of canals, that has been created in the tightening film (2).

The rough pressure surface (5) may be the texture of that of the pressure-plate or a rough coating applied or an embossed film or foil or a material of fibre with a regular rough texture. If the tightening film should not be crumple, the pressure points on the pressures surface has to be smooth and not cling the film.The valve is soundless until a pressure of about 50 hPa. It is necessary to protect the valve with an effective membrane

to provide, so the openings in the valve is not clogging and fluid substance forces it's way into the bag and furtherout into the valve and filter.

The preferred material for the membrane is Drylife™ fra W.L.Gore & Associates, Inc. with a proportion of pinhole about 2 – 3 μm or similar products, which has a membrane of non sintered polytetrafluorethylen on a porous, heatsealable bearing material. A sample from Gore has a thickness of the membrane of 0.035 mm. The membrane is 0.195 mm in another similar material for membranes. Both materials are hydrofobe and both materials can hardly be moistened by liquid from the intestinal, which during the night might have been collected in the bag. A test of moistening in a closed container of glass during 48 hours showed, that the last mentioned material with the thickest membrane rejected the liquid from the intestinal, somehow better than the sample from Gore. A material for membranes made of high-molecular polyethylen is moistened after few minutes from the intestinal liquid. The material for membranes from Gore with a 3 μm proportion of pinhole has a fine permeability of gas and at the same time is very, very tight against water.

The top of the valve (1) can be shaped as shown in figure 4, 5 and 6, partly to load the pressure plate equally, partly to improve the mechanical strength of the valve.

For a pressure control valve: the pressure of opening, the pressure of closing, the tightness of the valve, the flow through an open valve and the opening time of self closing valve, are depending both on the choice of material and on the design of such. Below are examples of design for pressure control valves as described.

Holes in films etc. down to 2 mm in diameter are made by a hand punching and to achieve smooth edges holes between 0.5 and 2 mm are to be made by punching. Smaller holes are made by a lancet-shaped needle, which gives an exactly defined hole with smooth cutting-shaped edges.

The opening pressure and the closing pressure for the valve is determined by measuring the decrease in pressure over the open valve in cm WC, when the valve is closing by decreasing pressure. The time is measured in seconds. Knowing the volume of the slot pipe pro centimetre, the volume flow in ml/min versus the pressure in WC can be calculated from the measured values and curves as shown in figure 22 can be plotted.

Measuring a valve, it is equipped with an extra bottom film (16) of a relative great circular opening (18) as shown in figure 7. The valve is glued to a plate of acrylic by double adhesive tape (17) over a hole with a pipe stub (20), leading to a pipe (21) on a metre of water column etc.

The valve in accordance with the inventing has a curve of flow or characteristic, which diverge from similar curves for deordorizing filter on stomibags plotted as curves marked a and b in figure 22. The flow increases strongly with the pressure through those filters. In practise no flow should be present below a pressure of 2 cm WC. An average flow from 1 – 3 ml/min should normally be satisfactory.

As mentioned six examples are included in the description of the figures. Examples described in figures 4 and 16 have curves of flow marked number 20f and 20j. Those curves are characteristic of the valve in accordance with the invention. These valves are opening by a pressure very close to zero and with such a low flow. Below a pressure of 2 cm WC it is impossible to distinguish from a small leaking or a controlled built-in leaking. The flow through the valves with curves marked f and j is measurable from around 1.5 cm WC and it only increases slowly with the pressure up to 5 – 6 cm WC. After this the flow will increase heavily with the pressure. The steep part of the curve is a result from a disappearing system of canals in the tightening film, originally built at a pressure of 2 – 5 cm WC. At this stage the film of tightening is gradually lifted from the bottom of the valve upwards due to the increasing static pressure in the bag.

The examples in figures 15 and 18 with the curves marked k and i are similar to the curves of flow marked f and j. On the other hand the curves of flow marked h diverge from the above described curves. The curve marked h is from the example discussed in figure 14. Figure 14 has a flow of 0.5 ml/min by a pressure of 4 cm WC. As earlier mentioned this could be an advantage for a valve on a stomybag, due to a very small opening (9) in the tightening film the flow through this valve increases more slowly, than the case of the four valves mentioned above.

Again the invention is described in the following with reference to the figures. The scale in the figures shown is almost chosen at random, especially the thickness of the components of the valve and there relative positions. Films, foils and membranes, which is an compound of more layers, is shown as a single line.

Figure 1 shows the components of the valve. In figure 2 is the valve assembled and attached to outside of a stomybag. The membrane is attached to the inside of the bag.

Figure 3 shows a valve, which closes in the direction of the gas pressure, consequential this valve is only to be opened manually.

Figure 4 shows a valve with a shaped and reinforced top (1). The protection membrane is attached to an extra bottom film on the edge of the opening (14). The bottom film (15) is further on attached to the edge of the valve (6).

Figure 5 and 6 show valves with a shaped top. They are built together with a filter of gas and they are also to be opened manually.

Figure 7 shows a valve, which is attached to a plate of acrylic for measurement.

Figure 8 and 9 show valves, which are opened manually.

Figure 10 shows a valve, which is hold open by the static pressure.

Figure 11 and 12 show a rectangular valve, which also can be opened manually.

Figure 13 shows a valve of that type, where the tightening film is not attached to the capsule of the valve or where the opening (9) in the tightening film (2) is lager than the opening (8) in the bottom of the valve (3).

Figure 14 shows a valve with a rough embossed pressure surface, which just is opened by a system of canals built by the static pressure in the bag.

Figure 15 shows a valve with an embossed pressure surface (5) and a circular opening (24) in the middle.

Figure 16 and 17 show a valve with a two-piece pressure plate (4, 7). This valve can also be opened manually.

In figure 18 and 19 has the pressure plate (4) a circular opening (23) in the middle.

Figure 20 shows how the flow through to the valve gradually decreases in the minutes, after the valve has been opened manually.

Figure 21 shows for discrete values of the external pressure on the bag, how the internal pressure in the stomybag depending on the degree of filling in the stomybag.

Figure 22 shows flow versus pressure for examples of valves, openings in gas filter for stomybags and needle holes.

Describing every single figure below, examples of valves in accordance with the invention is at the same time described in figures 4, 13, 14, 15, 16 and 18. The flow of the six valves versus pressure is shown in figure 22 as the curves marked f, g, h, i, j and k.

Unless nothing else is mentioned the valves described in these examples are circular with an internal diameter of 27 mm and sealed in a circular shaped heat sealing with a width of 3 mm.

Figure 1 shows the components of a pressure control valve. The top (1) and the bottom (3) of the valve forms a capsule of the valve. The tightening film (2), which in this case closes against the direction of the flow of gas, is attached to the bottom of the valve by the pressure plate (4) with the pressure surface (5). When the valve is open, the air flows through the openings (8, 9 and 10) respectively in the bottom of the valve, the tightening film and the top.

In figure 2 the valve is built together and heat sealed (6) in the edge of the opening (22) on the outside wall (11) of a stomybag. A protection membrane (12) is attached to the inside of the bag above the opening (22).

In figure 3 the tightening film (2) is placed in such a way, that the valve closes in the direction of the gas flow, This valve can only be opened manually, because the pressure plate (7) is made of viscous elastic material.

In figure 4 the top (1) of the valve is made of polyethylen (PE) film of 0.18 mm in thickness, which is heat shaped to give the valve a greater mechanical strength and to yield a equal pressure on the hole pressure plate (7). The protection membrane is heat sealed with a heatseable film on the edge (14), which again is attached to the edge of the valve (6).

A valve as shown in figure 4 is made of a top (1) as described above. The tightening film (2) is a PE film of 0.03 mm in thickness. The pressure plate (7) is made of viscous elastic foam with a thickness of 5 mm and a diameter of 12 mm. The pressure plate (5) is on the surface covered with a thin, non woven textile. The bottom film (3) is a 0.7 mm heatsealable film and the membrane (12) is heatsealable on one side. The round openings (8, 9 and 10) have diameters respectively of 2, 0.5 and 2 mm.

The flow versus pressure of this valve is shown as curve marked f in figure 22. The valve can be opened with a soft touch of a finger. The curve in figure 20 shows, how the flow through the valve falls in few minutes, after the valve has been opened.

Figure 5 shows a pressure control valve with separated pressure plate, which can be opened manually. The valve is built together with a filter of gas (13) and attached to the outside of the stomybag (11). The pressure plate is made of two parts. The one part is a soft foam plate (4), which is easily draws back by an over pressure in the bag, meanwhile the other part consists of viscous elastic foam (7), being pressed flat the valve opens and by a delay of time closes again. The flat gas filter is glued or heat sealed to the top of the valve (1) with the opening (30) in the middle of the filter (13). The opposite surface of the filter is covered of a gas tight membrane (27). The filter is open along its periphery (29). The protection membrane of the filter (12) has a heat sealing (14) to the bottom of the valve (3).

Figure 6 shows a valve of similar construction as the valve described in figure 5, but in this case the valve is fastened to the inside of a stomybag. The pressure plate (4) with the surface (5) keeps the pressure below the opening pressure of the valve, meanwhile the other part of the pressure plate (7) is made of viscous elastic foam. This part of the valve can also be opened manually.

Figure 11 shows a valve of rectangular shape, which is similar to the example of a valve described in figure 16. The rectangular shape is appropriated, because the valve can be made in strips, which can be cut up into valve pieces and heat sealed at the endings.

In figure 13 is the opening (9) in the tightening film (2) much bigger than the opening (8) in the bottom of the valve (3). The tightening film may have the same area as the pressure plate and can in this case not be fastened to the top of the valve.

In an example given of such valve the three films of top, bottom and tightening are of the same thickness, namely 0.07 mm. The diameter of the tightening film as well as the diameter of the pressure plate is 20 mm. The thickness of the pressure plate is 2 mm and it is made of a light and soft foam. The openings (8 and 10) are both 3 mm in diameter. The flow versus pressure for the valve is shown as the curve marked g in figure 22.

When the opening (9) as in this case is much bigger than the opening (8) and the pressure surface (5) is made of a relative smooth and fine celled foam, the valve gets a higher pressure of opening and closing. When on the opposite side the opening (9) is much smaller than the opening (8) in the bottom (3) of the valve and the pressure surface (5) is especial rough, the valve gets a lower pressure of opening and closing. The magnitude of this pressure is also ruled by choice of dimensions of the valve, the thickness and quality of the used films, the strength of the press of the pressure plate against the tightening film and the elasticity and the dimensions and shape of the pressure plate etc.

In figure 14 the pressure surface (5) is an embossed polyethylenfilm with a depth of the embossing of around 0,5 mm. The distance between the top points or press points (25) is 1,5 mm.

The pressure surface (5) in a valve is an embossed film like that, meanwhile the pressure plate (7) is made of 4 mm in thick viscous elastic foam. The pressure plate with pressure surface is 10 mm in diameter. The three films (1, 2 and 3) are all 0,7 mm in thickness. The openings (8 and 10) are both 2 mm in diameter, meanwhile the opening (9) in the tightening film (2) is a little hole made by a needle. Flow versus pressure of the valve is plotted as curve marked h in figure 22. This valve can not close tight, because the pressure surface is too small and too rough. The pressure surface can limit the magnitude of the flow from the bag through the valve and the filter considerable, because the opening (9) in the tightening film is very small and is determining for the magnitude of the flow at 11 cm WC the flow is 5 ml/min. The valve can be opened manually.

In figure 15 are the three films (1, 2 and 3) all 0.7 mm in thickness, and the openings (8, 9 and 10) measure respective 4, 0.5 and 4 mm in diameter. The pressure plate is made of a light and elastic foam with an open celled structure. The pressure plate is 2 mm in thickness and 20 mm in diameter. The pressure surface (5) is made of an embossed film as mentioned above. The embossed pressure surface is 20 mm in diameter and has a round hole in the middle (24) with a diameter of 6 mm. The curve for flow versus pressure for the valve is plotted in figure 22 marked i..

The valve in figure 16 and 17 has a divided pressure plate (4, 7). The one part (4) is a soft foam (4) and measure 6x20x2 mm. The other part (7) is made of viscous

elastic foam and measure 6x20x3 mm. Top and bottom films are 0.7 mm in thickness and the tightening film is 0.03 mm in thickness. The opening (8) in the bottom of the valve consist of two holes each with a diameter of 2 mm. The holes are moved to the periphery of the valve as shown in figure 17. The two openings (9) have different magnitudes. The opening below the viscous elastic foam is 0.5 mm in diameter, meanwhile the other hole is a cut by a needle. The curve marked j for flow versus pressure for the valve is shown in figure 22. The valve can be opened manually. The rectangular valve can be made in strips.

The valve in figure 18 and 19 has a round pressure plate of soft foam. It is 2 mm thick and 24 mm in diameter. The pressure plate has a circular opening (23) in the middle with a diameter of 12 mm. The top and bottom film of the valve is 0,7 mm in thickness and the tightening film is 0,03 mm in thickness. The openings (8, 9 and 10) are respective 4, 0,5 and 2 mm in diameter.

When the valve is attached with double adhesive tape on a plate of acrylic as shown in figure 7, it is possible to see, what happens, when the valve is exposed for pressure through the opening (8) in the bottom (3) of the valve. Even by a pressure of 30 hPa the bottom film hardly moves. On the other hand a pressure on the tightening film no more than 5 cm WC visible arch up over the bottom of the valve beyond the opening of 12 mm (23) in the pressure plate (4). A part from this valve opens very easily by a small flow at 2-3 cm WC and closes easily by 1.5 cm WC. The curve marked k for the flow in the valve is shown in figure 22. The valve has a flow at least 5 ml/min by 5 cm WC.

Figure 20 shows how the magnitude of the flow through an opened valve falls as function of time, while the viscous pressure plate expands, after being flattened by a finger.

In figure 21 shows, how the internal pressure in the stomybag depends of the degree of filling by discrete values of the external pressure on the bag.

Figure 22 shows flow versus pressure for the gas filter on the stomybags, small holes and valves in accordance with the invention. The gas filter from two different stomybags has by 10 cm WC a flow of 540 ml/min and 31 ml/min. There curves of flow are marked a and b. The curve marked c is from a 0.002 sq.mm hole in a foil of copper of 0.1 mm in thickness. The curves marked d and e are holes cut by a needle, which has

been made by a needle of a shape as lancet in a PE-film of 0.03 mm in thickness. The cut in for curve marked d is 0.56 mm in length and the cut in for curve marked e is of 0.43 mm in length. The direction of curvature for these curves shows, that the area of the hole increases by the pressure for holes with a cut-shape. The other curves concern examples of valves, which has been described under the figures 4, 13, 14, 15, 16 and 18.

CLAIMS

1. A valve for automatic ventilation of stomybags or any confined gas as shown in figure 2, a valve mainly produced of elastic and viscoelastic, polymeric materials of porosity, which does not deform plastic under normal use, a valve opening and closing within a fixed interval of pressure above the atmospheric in the gas, a valve, when provided with a viscoelastic pressure sheet, for manual opening as well and after a period of time closing continually and a valve, which can be used separately, in combination with a gas filter or built together with a gas filter, characterized by the combination, that

a. the tightening film (2), at a pressure below the limit of pressure for opening the valve, will close the valve, in the direction of the pressure in such a way, that the opening (10) in the top of the valve is constantly opened, but the openings (8) in the bottom of the valve and the opening (9) in the film of tightening one or both are held closed, owing to the tightening film is hold down against the bottom of the valve (3), by the elastic power from the top of the valve (1), in combination with the elastic power from the pressure plate (4) and its pressure surface (5), that

b. the protection membrane (12), which covers the opening (8) in the bottom (3) of the valve, is fixed to bottom or is fixed to the internal side of the bag above the opening (22) in the wall of the bag, that

c. the pressure plate (4) may have of a rough, celled structure or been given an other, rough surface, that

d. the pressure surface (5) may be made as a separate, embossed film, foil or textile.

2. The valve in accordance with claim 1, characterized by a pressure plate or a part of the plate impregnated with activated carbon and having a gas tight coating or a film covering the parallel surfaces of the plate.

3. The valve in accordance with claim 1, characterized by a tightness of the valve is secured by impregnation with a non volatile liquid on one or both of its two closing surfaces.

4. The valve in accordance with claim 1, characterized by, a controlled, low flow at a closed state of the valve, when one or both surfaces of closing

on the tightening film and the bottom of the valve has been given a rough or embossed structure.

5. The valve in accordance with claim 1, c h a r a c t e r i z e d by a tightening film placed over the pressure plate for closing the valve in the direction of the pressure of gas in such way, that the valve may only be opened manually.

6. The valve in accordance with claim 1, c h a r a c t e r i z e d by a top of the valve (1) formed in such a way, that the top get a greater mechanical strength than an unformed top gives an equal weight on the pressure surface.

7. The valve in accordance with claim 1, c h a r a c t e r i z e d by a top of the valve (1) been made of elastic textile, which can be heat sealed.

8. The valve in accordance with claim 1, c h a r a c t e r i z e d by a bottom film of the valve (3) and a tightening film (2) having openings (8 and 9), where these openings shall have smooth and not deformed edges , where the diameter of the opening (8) may be up to half of the diameter of the pressure plate (4), and where the opening (9) may be a hole formed as a cut made by a needle formed as a lancet.

Figure 1

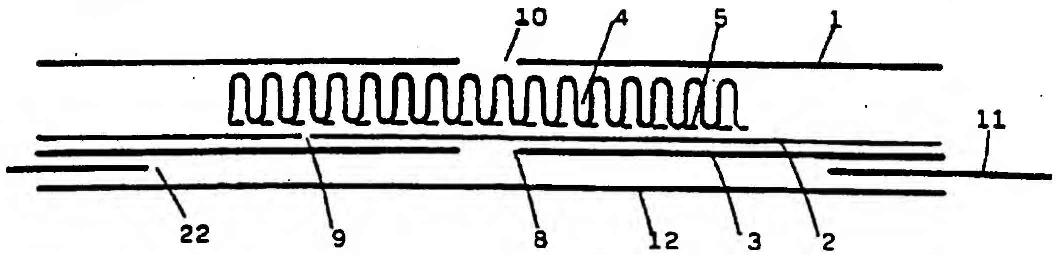
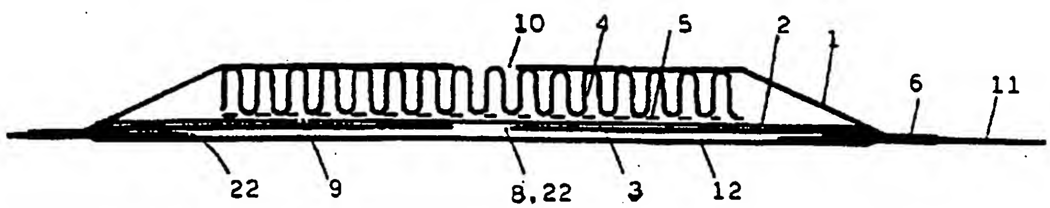


Figure 2



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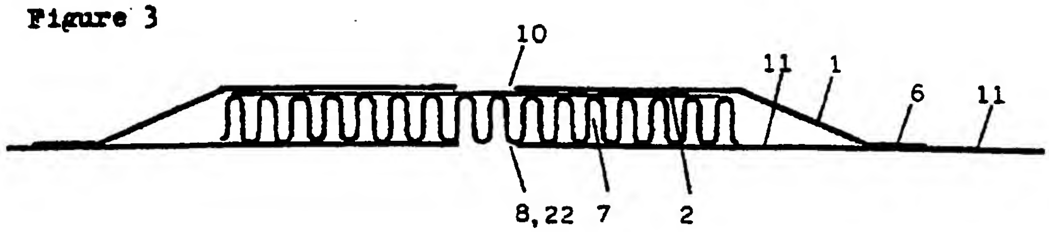


Figure 4

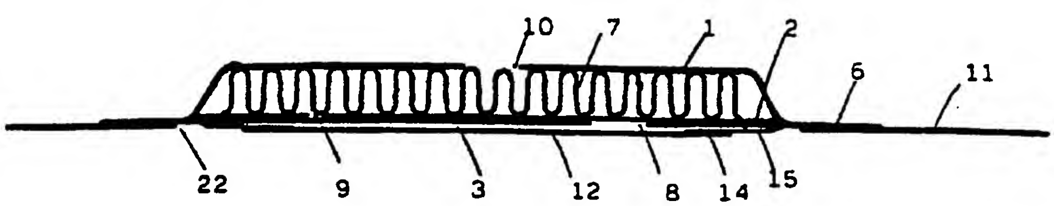


Figure 5

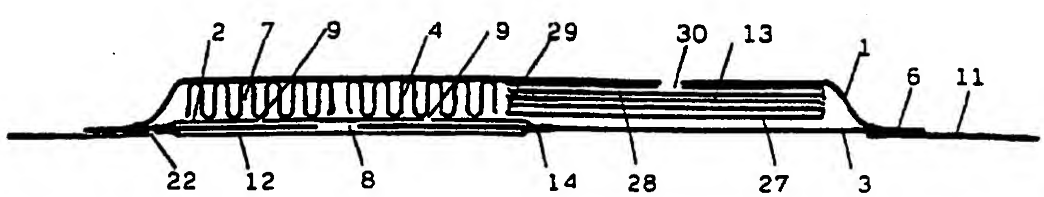


Figure 6

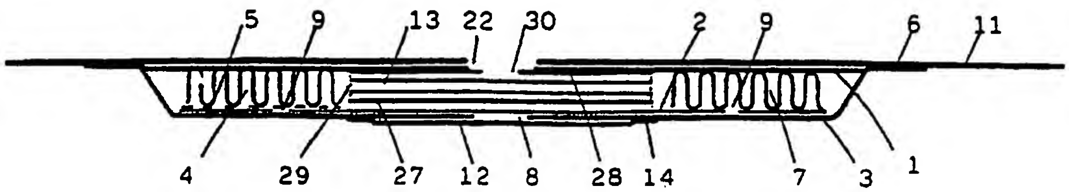


Figure 7

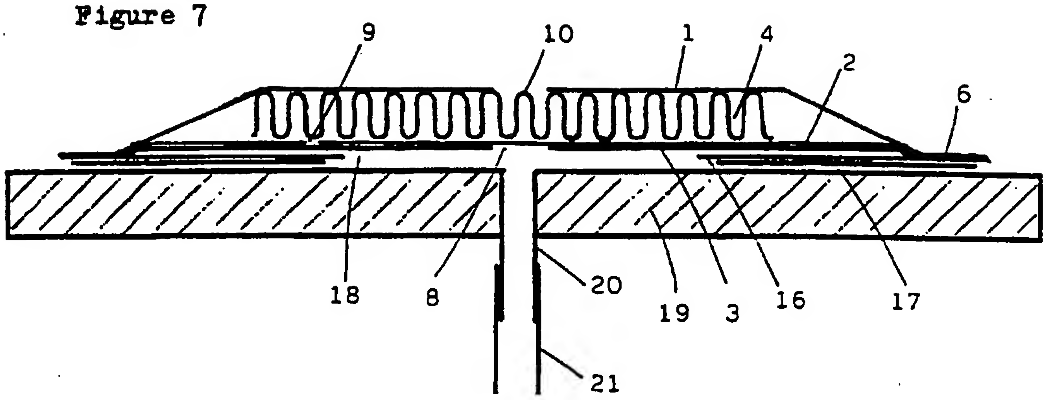


Figure 8

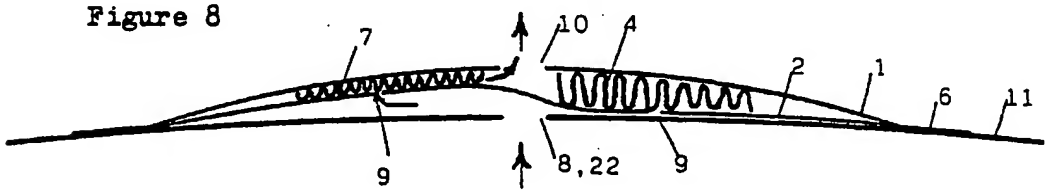


Figure 9

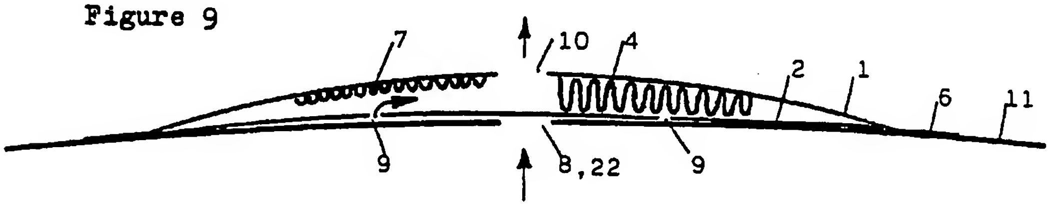


Figure 10

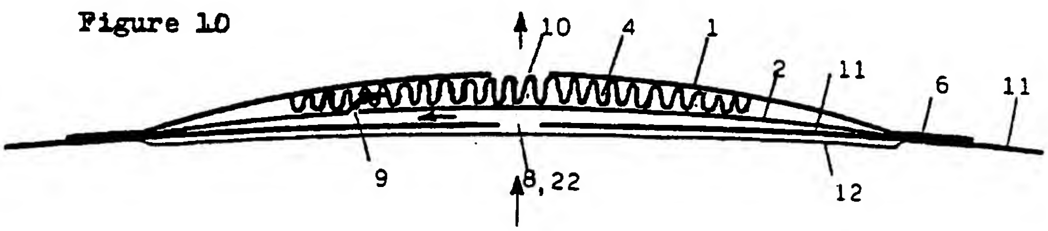


Figure 11

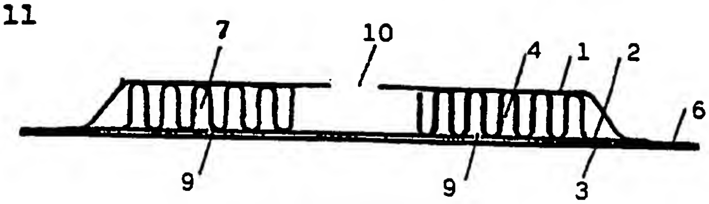


Figure 12

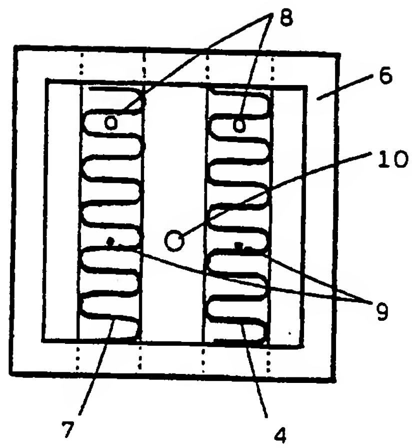


Figure 13

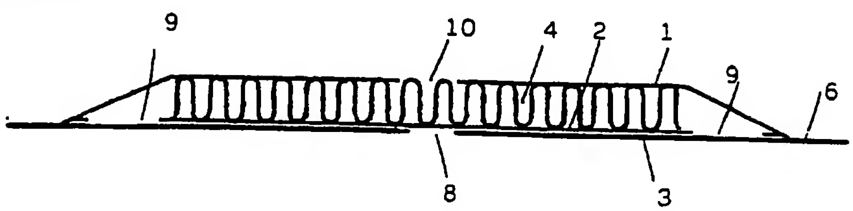


Figure 14

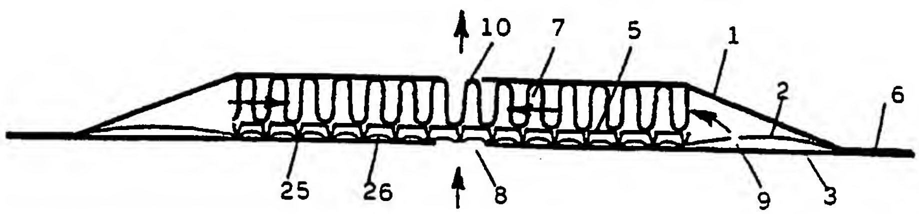


Figure 15

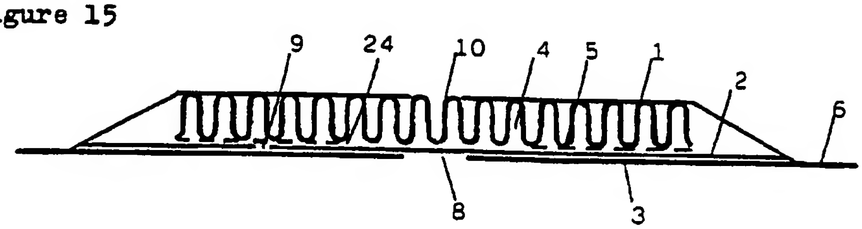


Figure 16

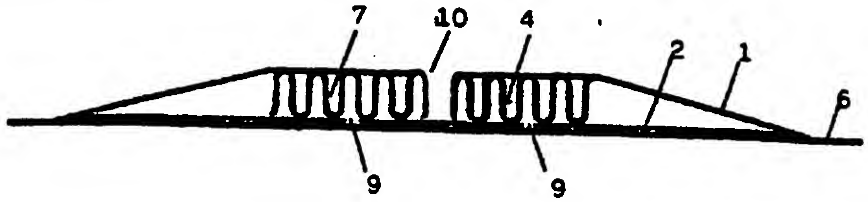


Figure 17

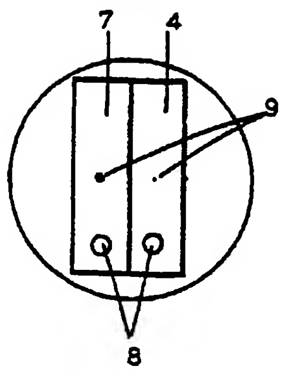


Figure 18

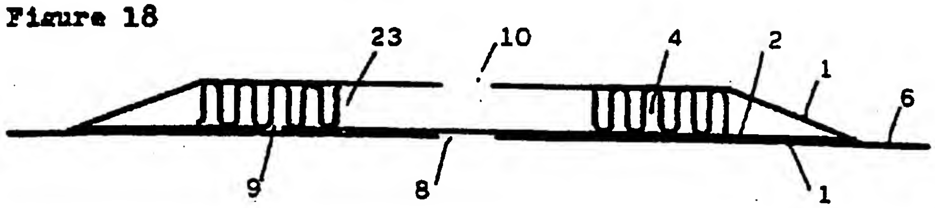


Figure 19

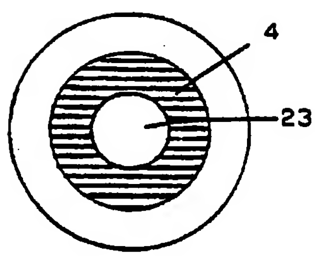
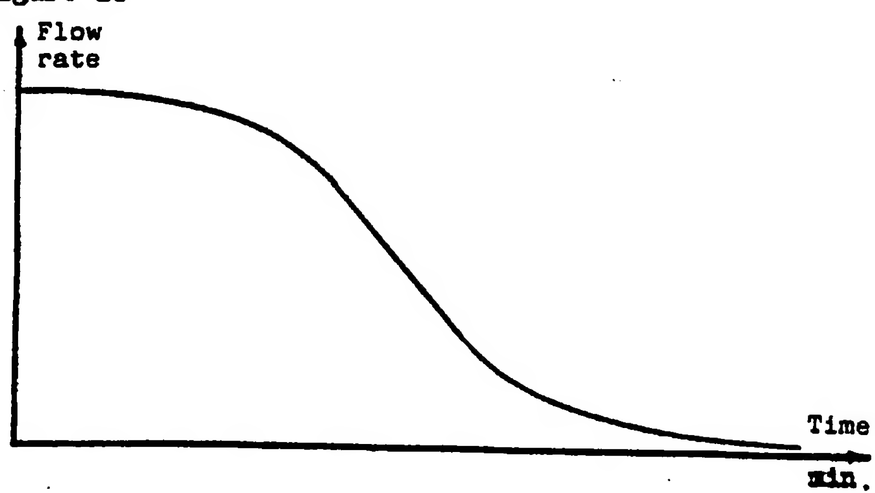


Figure 20



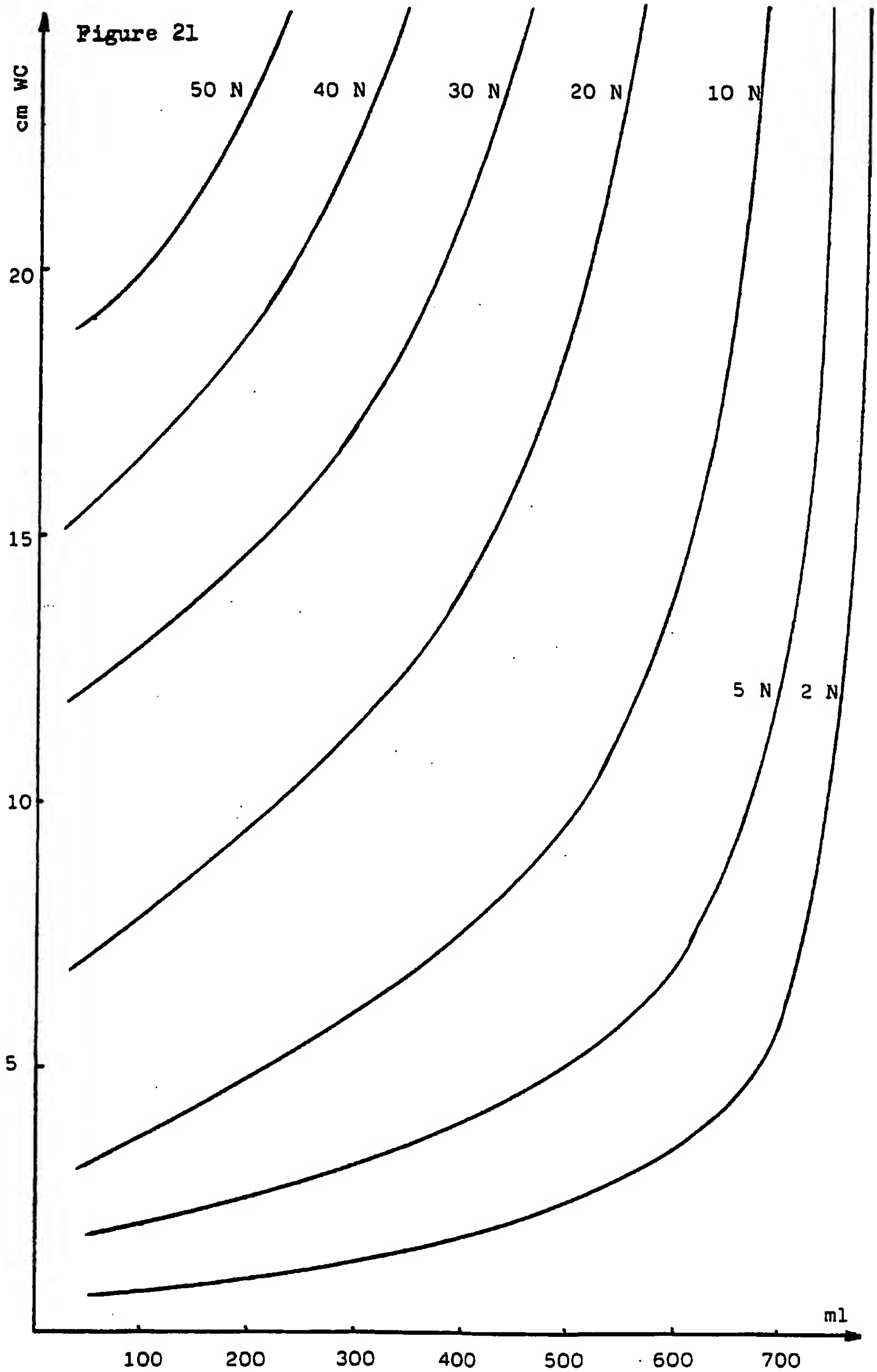
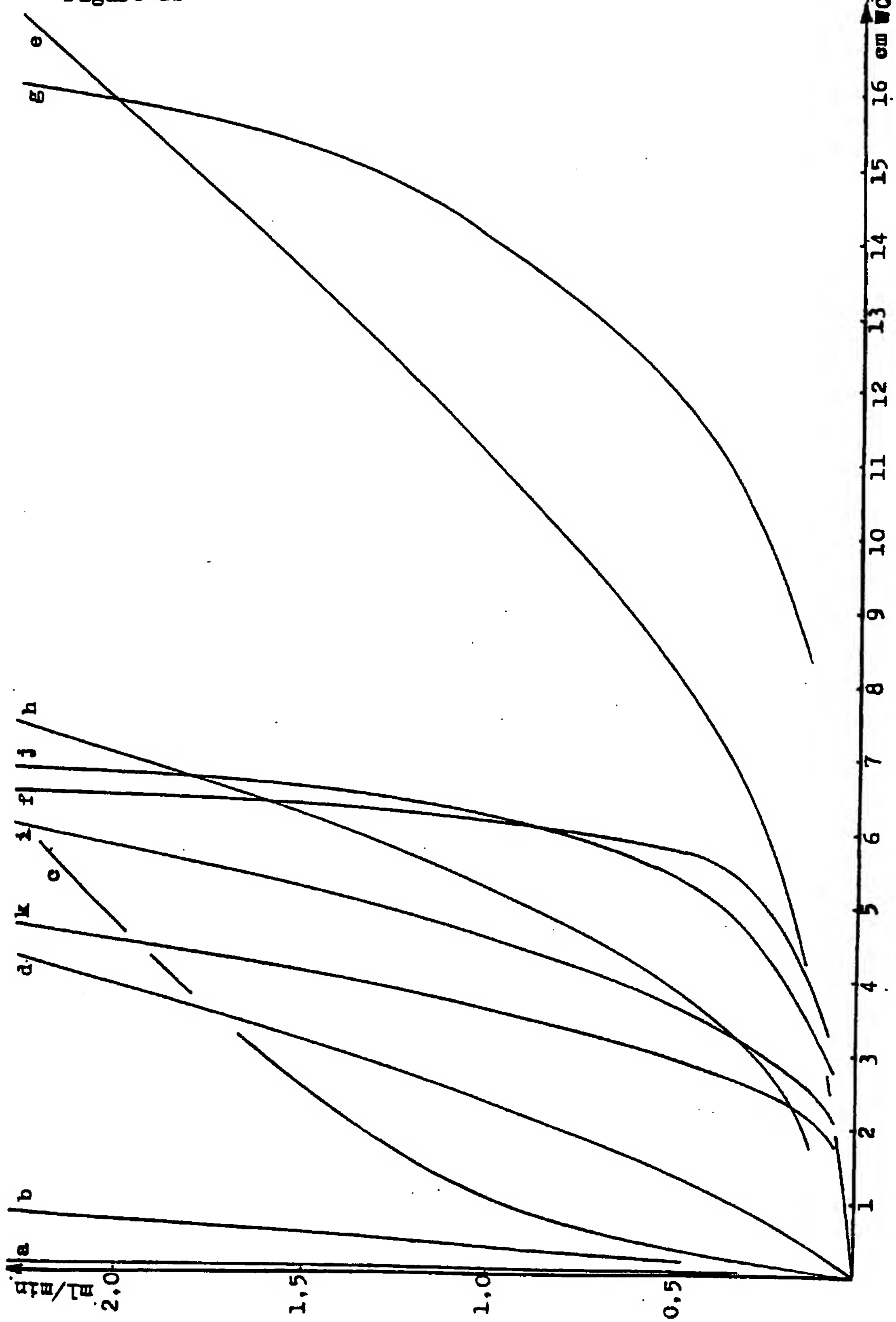


Figure 21
cm WC
50 N
40 N
30 N
20 N
10 N
5 N
2 N
20
15
10
5
ml
100
200
300
400
500
600
700

Figure 22


ml/min
2,0
1,5
1,0
0,5
cm WC
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
a
b
c
d
e
f
g
h
i
j
k

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 00/00607

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61F 5/441

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC,MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	GB 2094153 A (JOHNSON AND JOHNSON), 15 Sept 1982 (15.09.82), figures 2-6, abstract --	1
X	US 5626569 A (HENRI HOLTERMANN ET AL), 6 May 1997 (06.05.97), column 6, line 36 - column 7, line 47, figures 5-7,14 --	1-2

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed
- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 March 2001	23 -03- 2001
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Leif Brander/MP Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 00/00607

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	GB 2296660 A (WELLAND MEDICAL LIMITED), 10 July 1996 (10.07.96), figure 2, abstract --	1-8
A	US 4460392 A (FINN POULSEN ET AL), 17 July 1984 (17.07.84), figure 3, abstract -- --------	1-8

INTERNATIONAL SEARCH REPORT
Information on patent family members

25/02/01

International application No.
PCT/DK 00/00607

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